a pulse form that produces subthreshold stimulation by selectively stimulating regions of the cerebral cortex of approximately 1-2 cm (the estimated size of a "functional unit" of cortex), directly contacting the pial surface with the electrodes to consistently create the same alterations in resting membrane potential, and/or biasing the electrodes against the pial surface to provide a positive connection between the electrodes and the cortex.

B. Devices for Electrically Stimulating Regions of the Brain

Figures 6-40 illustrate stimulation apparatus in accordance with several embodiments of the invention for electrically stimulating regions of the brain in accordance with one or more of the methods described above. The devices illustrated in Figures 6-40 are generally used to stimulate a region of the cortex proximate to the pial surface of the brain (*e.g.*, the dura mater, the pia mater, the fluid between the dura mater and the pia mater, and a depth in the cortex outside of the white matter of the brain). The devices can also be adapted for stimulating other portions of the brain in other embodiments.

1. Implantable Stimulation Apparatus with Integrated Pulse Systems

Figure 6 is an isometric view and Figure 7 is a cross-sectional view of a stimulation apparatus 600 in accordance with an embodiment of the invention for stimulating a region of the cortex proximate to the pial surface. In one embodiment, the stimulation apparatus 600 includes a support member 610, an integrated pulse-system 630 (shown schematically) carried by the support member 610, and first and second electrodes 660 (identified individually by reference numbers 660a and 660b). The first and second electrodes 660 are electrically coupled to the pulse system 630. The support member 610 can be configured to be implanted into the skull or another intracranial region of a patient. In one embodiment, for example, the support member 610 includes a housing 612 and an attachment element 614 connected to the housing 612. The housing 612 can be a molded casing formed from a biocompatible material

that has an interior cavity for carrying the pulse system 630. The housing can alternatively be a biocompatible metal or another suitable material. The housing 612 can have a diameter of approximately 1-4 cm, and in many applications the housing 612 can be 1.5-2.5 cm in diameter. The housing 612 can also have other shapes (e.g., rectilinear, oval, elliptical) and other surface dimensions. The stimulation apparatus 600 can weigh 35g or less and/or occupy a volume of 20cc or less. The attachment element 614 can be a flexible cover, a rigid plate, a contoured cap, or another suitable element for holding the support member 610 relative to the skull or other body part of the patient. In one embodiment, the attachment element 614 is a mesh, such as a biocompatible polymeric mesh, metal mesh, or other suitable woven material. The attachment element 614 can alternatively be a flexible sheet of Mylar, a polyester, or another suitable material.

Figure 7, more specifically, is a cross-sectional view of the stimulation apparatus 600 after it has been implanted into a patient in accordance with an embodiment of the invention. In this particular embodiment, the stimulation apparatus 600 is implanted into the patient by forming an opening in the scalp 702 and cutting a hole 704 through the skull 700 and through the dura mater 706. The hole 704 should be sized to receive the housing 612 of the support member 610, and in most applications, the hole 704 should be smaller than the attachment element 614. A practitioner inserts the support member 610 into the hole 704 and then secures the attachment element 614 to the skull 700. The attachment element 614 can be secured to the skull using a plurality of fasteners 618 (*e.g.*, screws, spikes, etc.) or an adhesive. In an alternative embodiment, a plurality of downwardly depending spikes can be formed integrally with the attachment element 614 to define anchors that can be driven into the skull 700.

The embodiment of the stimulation apparatus 600 shown in Figure 7 is configured to be implanted into a patient so that the electrodes 660 contact a desired portion of the brain at the stimulation site. The housing 612 and the electrodes 660 can project from the attachment element 614 by a distance "D" such that the electrodes 660 are positioned at least proximate to the pia mater 708 surrounding the cortex 709.

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The electrodes 660 can project from a housing 612 as shown in Figure 7, or the electrodes 660 can be flush with the interior surface of the housing 612. In the particular embodiment shown in Figure 7, the housing 612 has a thickness "T" and the electrodes 660 project from the housing 612 by a distance "P" so that the electrodes 660 press against the surface of the pia mater 708. The thickness of the housing 612 can be approximately 0.5-4 cm, and is more generally about 1-2 cm. The configuration of the stimulation apparatus 600 is not limited to the embodiment shown in Figures 6 and 7, but rather the housing 612, the attachment element 614, and the electrodes 660 can be configured to position the electrodes in several different regions of the brain. For example, in an alternate embodiment, the housing 612 and the electrodes 660 can be configured to position the electrodes deep within the cortex 709, and/or a deep brain region 710. In general, the electrodes can be flush with the housing or extend 0.1 mm to 5 cm from the housing. More specific embodiments of pulse system and electrode configurations for the stimulation apparatus will be described below.

Several embodiments of the stimulation apparatus 600 are expected to be more effective than existing transcranial electrical stimulation devices and transcranial magnetic stimulation devices. It will be appreciated that much of the power required for transcranial therapies is dissipated in the scalp and skull before it reaches the brain. In contrast to conventional transcranial stimulation devices, the stimulation apparatus 600 is implanted so that the electrodes are at least proximate to the pial surface of the brain 708. Several embodiments of methods in accordance with the invention can use the stimulation apparatus 600 to apply an electrical therapy directly to the pia mater 708, the dura mater 706, and/or another portion of the cortex 709 at significantly lower power levels than existing transcranial therapies. For example, a potential of approximately 1 mV to 10 V can be applied to the electrodes 660; in many instances a potential of 100 mV to 5 V can be applied to the electrodes 660 for selected applications. It will also be appreciated that other potentials can be applied to the electrodes 660 of the stimulation apparatus 600 in accordance with other embodiments of the invention.